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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,861	09/05/2003	Yi Wang	ALXN-PO1-102	7250

28120 7590 03/13/2007

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/655,861	WANG, YI	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *23,26,29-31,33 and 35-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24,25,27,28,32,34 and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060925, 20060309, 20040628*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application claims the benefit of the filing date of provisional applications 60/408,571 and 60/469189.

New claims 45-50 have been added.

Claims 1-50 are currently pending.

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-21, 22, 24, 25, 27, 28, 30, 32, 34, 36-40 and 43, in the reply filed on November 13, 2006 is acknowledged.

Claims 30, 36-40 and 43 were marked by Applicant as being withdrawn. However, these claims are still being examined to the extent that they read upon anti-C5 antibodies. Applicant should amend the claims accordingly.

2. Claims 23, 26, 29, 31, 33, 35, 41, 42 and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 13, 2006.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-22, 24, 25, 27, 28, 30, 32, 34, 36-40, 43 and 45-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/127,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '438 application are similarly drawn to the treatment of inflammatory conditions, including asthma, using anti-complement antibodies, including antibodies to the C5 complement component.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 21 is a relative term that renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Fitch et al. (Circulation (1999) 100:2499-2506; U on form PTO-892).

Fitch teaches that coronary bypass surgery (CBP) elicits a systemic inflammatory response (page 2499, column 1 in particular). Fitch teaches a method of administering of a humanized single chain monoclonal antibody directed to human complement component C5 (h5G1.1-scFv) to subjects

undergoing CBP. The h5G1.1-scFv antibody is a complement inhibitor that binds to complement component C5 and prevents the cleavage of C5 into C5a and C5b (Fitch page 2500, column 1 in particular). Fitch teaches that h5G1.1-scFv treatment inhibited pathological complement activation and had a pronounced anti-inflammatory effect (page 2504, column 2 in particular). The prior art teaching anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-10, 18, 22, 24, 25, 27, 28, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032; CP on form PTO-1449 filed 9/25/2006) in view of

Drouin teaches that C5a receptors are increased on bronchial epithelial and smooth muscle cells in sepsis and in asthma (Abstract in particular). Drouin teaches that septic primates and rats that are treated with anti-C5a antibodies have reduced pulmonary edema and lung injury (page 2031, first column in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to treat subjects with asthma using an antibody that inhibits C5 or C5a based upon the teachings of Drouin. One would have been motivated to do so with a reasonable expectation of success by the teachings of Drouin that treatment of similar inflammatory events in sepsis with anti-C5a antibodies reduced edema and damage in the lungs.

8. Claims 11-13, 15, 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032; CP on form PTO-1449 filed 9/25/2006) as applied to claims 1-9 above, and further in view of Fitch et al. (Circulation (1999) 100:2499-2506; U on form PTO-892).

Drouin has been discussed supra.

Drouin does not teach the treatment of human subjects or the h5G1.1 antibody.

Fitch has been discussed supra.

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to use the h5G1.1 antibody to treat airway inflammation in a human subject, such as one with asthma. One would have been motivated to combine the teachings for the treatment of human asthma patients with a reasonable expectation of success by the teachings of Drouin that anti-C5a antibodies reduce lung injury and edema in sepsis that are similar to the injuries seen in asthma and the teachings of Fitch that h5G1.1 antibody is effective for the treatment of inflammation-related injuries in human patients.

9. Claims 17 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032; CP on form PTO-1449 filed 9/25/2006) as applied to claims 1-9 above, and further in view of U.S. Patent 4,228,795 to Babington (A on form PTO-892).

Drouin has been discussed supra.

Drouin does not teach a disperser for dispersing an aerosol.

The '795 patent teaches a nebulizer which can be used to aerosolize medicants for nasal inhalation (Figure 4 and column 6, line 7 through column 8, line 54 in particular). The '795 patent further teaches that said nebulizer is suitable for use with viscous or sticky substances (column 8, lines 34-37 in particular). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the nebulizer taught by the '795 patent to administer the anti-C5a antibodies taught by Drouin. One would have been motivated with a reasonable expectation of success to administer the antibodies directly to the respiratory mucosa, which is often the first line of encounter of an immune system with pathogenic organisms and by the teachings of the '795 patent that the nebulizer is usable with sticky substances, which a common property of proteinaceous solutions.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
February 5, 2007

DAVID A. SAUNDERS
PRIMARY EXAMINER